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FILED

APR - 3 2014

Clerk, U S District Court
District Of Montana
Billings

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MONTANA

TOBY C. MCADAM,

Plaintiff,

vs

UNITES STATES FOOD AND DRUG
ADMINSTRATION; MARGARET
HAMBUR, COMMISSIONER OF FDA;
CHARLES BREEN, DIRECTOR OF
SEATTLE DISTRICT OF FDA; MARIAM
R. BURBACH, ACTING DIRECTOR OF
SEATTLE DISTRICT OF FDA; LISA
ALTHAR, COMPLIANCE OFFICE OF
SEATTLE DISTRICT OF FDA; et. al,

Defendants.

Cause No. CV-14-47-BK-SPW-CSO

COMPLAINT

JURY TRIAL DEMANDED

COMPLAINT

I. JURISDICTION

This court has jurisdiction pursuant to 28 U.S.C. § 1331, Federal Question, raises claim arising under Constitution, laws, or treaties of the United States and the state of Montana. Remedies may be sought against a federal agency under the Federal Tort Claims Act against its employees. Under the Federal Tort Claims Act § 1346(b) and 2401 (b). Additionally, under *Bivens v. Six Unknown Named Agents*, 403 U.S. 388 (1971), was a case in which the United States Supreme Court ruled that an implied cause of

action existed for an individual whose Fourth Amendment freedom from unreasonable search and seizures had been violated by federal agents. The victim of such a deprivation could sue for the violation of the Amendment itself, despite the lack of any federal statute authorizing such a suit. The existence of a remedy for the violation was implied from the importance of the right violated. Plaintiff asserts that Defendants not only violated numerous Constitutional and Statutory laws but also breached of contract.

II. EXHAUSTION OF ADMINSTRATIVE REMEDIES

A. No cause alleged in this Complaint requires exhaustion of administrative remedies before filing Complaint.

B. Plaintiff asserts that he did in fact attempt resolve the issues and allegations raised in the Complaint through the administrative process.

III. PARTIES TO CURRENT LAWSUIT

A. Plaintiff Toby C. McAdam is proceeding pro-se and is a citizen of Montana presently residing at 105 S. 9th Street, Livingston Montana 59047 whom has a viable interest in this lawsuit and was directly effected by the actions of the Defendants.

B. Defendant Margaret Hamburg is employed as commissioner of the Food and Drug Administration 10903 New Hampshire Ave Silver Spring, MD 20993-0002 of Maryland and is a citizen of the United States and is employed as Commissioner of the United States Food and Drug Administration and is responsible for supervising those agents and employees that work or are employed by the United States Food and Drug Administration.

C. Charles Breen, was employed at the Food and Drug Administration

Seattle District Office 22215 26th Ave SE, Suite 210 Bothell, WA 98021 and is a citizen of the United States and was Director of the Seattle District of the United States Food and Drug Administration and is responsible for overseeing the actions of agents and compliance officers that are under supervision of the Seattle District of the Food and Drug Administration.

D. Mariam Burbach, is employed at Food and Drug Administration Seattle District Office 22215 26th Ave SE, Suite 210 Bothell, WA 98021 and is a citizen of the United States as Director of the Seattle District of the United States Food and Drug Administration and is responsible for overseeing the actions of agents and compliance officers that are under supervision of the Seattle District of the Food and Drug Administration.

E. Lisa Althar, is employed at the Food and Drug Administration Seattle District Office 22215 26th Ave SE, Suite 210 Bothell, WA 98021 and is a citizen of the United States and is a compliance office at the Seattle District of the United States Food and Drug Administration she has the discretion to decide if those dietary and nutritional supplement companies are in compliance with the Dietary Supplement Act in the Seattle District.

F. Those other Defendants that will be made part of this law suit whom that are employed or acted in concert or as agents with or for the United States Food and Drug Administration.

G. All Defendants that are named in this lawsuit or become part of this lawsuit are held responsible by their actions in their official, unofficial and/or individual

capacity as agents, officials or acting in concert with the United States Food and Drug Administration.

IV. STATEMENT OF CLAIMS

A. Count 1. Plaintiff alleges that Defendants violated and continue to violate his right to equal protection and treatment under the Constitutions, laws and treaties of the United States and the State of Montana.

Date of Incident: The violations started on or about May 2007 and continues to present.

1. Supporting facts: From on or about May 2007 to present, Defendants notified Plaintiff that the dietary supplements his company produced violated the Dietary Supplement Act and the United States Food and Drug Administration regulating Dietary and Nutritional Supplements. Defendants specifically addressed the wording on the labels of his products and his web site. Plaintiff addressed those specific issues raised by the Defendants and submitted those changes to the Seattle Division of the United Food and Drug Administration. On or about March 2008, Plaintiff was served another warning letter again stating he was in violation of the United States Food and Drug Administrations regulations regarding dietary and nutritional supplements wording claims on the web sites and wording on the product labels. Again, Plaintiff addressed those issues and submitted those changes to the Seattle Division of the United States Food and Drug Administration. Plaintiff requested a letter or document from Defendant Lisa Althar stating the changes submitted were either in compliance or not in compliance,

Ms Althar stated that it is not the policy of the United States Food and Drug Administration to provide correspondence as to whether changes made are in compliance or not. Then on or about May 2009, Plaintiff was served yet another warning letter stating his labels and wording on his web site were in violation of the United States Food and Drug Administrations regulations regarding dietary and nutritional supplements, again Plaintiff submitted changes that were specifically address in the letter. This time, Plaintiff used referred to wording on labels and web sites from other dietary supplement companies such as Now Foods, GNC and Natures Sunshine just to name a few. Plaintiff submitted those the changes to Lisa Althar of the Seattle Division of the United Food and Drug Administration, again Plaintiff was informed that he would not receive any correspondence as to whether the wording on his labels or web site were compliant. Then on or about November 2010 Plaintiff was persuaded with threats of incarceration that if he did not sign the consent decree. On or about November 2010, Plaintiff entered into a contract with Defendants by the way of a consent decree. A consent decree is a contract between two parties that stipulates what is expected of each party. Plaintiff challenged the validity of the consent decree, he raised issues such as signing the consent decree under threats of intimidation and coercion, and under the influence of prescription pain medications, however the court held that it was a valid and binding contract.

B. Count II. Plaintiff alleges that Defendants breached sections of the Consent Decree.

Date of Incident: The violations started on or about November 2010 and continues to present.

1. Supporting facts: On or about November 2010 Plaintiff and Defendants entered into a contract in the form of a consent decree. Plaintiff challenged the validity of the consent decree, numerous issues were raised. Those being, Plaintiff signed the consent decree under threats of coercion and intimidation. Plaintiff even raised the fact that he was on a pain management protocol, that being medications of Oxycotin, Oxycodone and Hydrocodone. Though all the issues were raised and medical documents submitted as to the effects of pain medications, the court decided it was a valid and binding consent decree, ie contract. Therefore, since it is a valid contract in the eyes of the court, both parties must be held to the same standards. One of the sections of the Consent Decree was that the Plaintiff was to secure an outside source or expert to prepare or review has labels before submitting them to the Seattle District of the Food and Drug Administration. Plaintiff contacted Lisa Althar of the Seattle District of the United Food and Drug Administration and asked what is required or constitutes a label expert, she stated that they can not be employed or be affiliated with Plaintiff's company. Plaintiff provide Ms Althar with the name of Carol Kreigle as the outside label expert, Ms Althar talked with Ms Kreigle and stated she would be acceptable. Plaintiff submitted his labels prepared by the outside label expert to Lisa Althar. Plaintiff contacted Ms Althar and asked when written documentation would be sent regarding the labels, Ms Althar stated that it is not the policy of the United States Food and Drug Administration to provide anything in writing regarding as whether a company's labels are compliant or not; hence the first violation of the consent decree. Based on the response Plaintiff believed he was in compliance with the FDA, he then resumed the manufacture and selling of nutritional supplements. Defendants filed a motion in court requesting that Plaintiff had violated the

consent decrees regarding retaining an outside label expert and requested that a fine of eighty thousand dollars be levied, the court ruled. Plaintiff asserts that when Defendants refused to accept the labels they should have informed him in writing so he could have retained an other source. Defendants did not notify Plaintiff. Plaintiff has documents and recordings of phone conversations as to the fact that Defendants stated that the outside label expert was acceptable. With the levying of the fine is evident that the Defendants were the first to violate the consent decree, Plaintiff had ceased all operations up to the point of when he submitted the labels to Ms Althar and was in full compliance. On or about November 2010 an inspection by an agent representing the Defendants arrived and Plaintiffs office to destroy the black salve and make sure he was not selling or producing products that were effected by the consent decree, all sale and production had ceased.

C. Count III. Plaintiff alleges that Defendants do not have jurisdiction when he sells his products inside the state he resides; interstate versus intrastate.

Date of incident: On or about November 2010 to present.

1. Supporting facts: One of the provisions in Consent decree signed on or about November 2010 stated that Plaintiff could not sell black salves. Defendant discontinued selling black salves. However on or about October 2013 at a just cause hearing the Defendants alleged that Plaintiff had sold black salve to a health store in Bozeman Mt. It was documented that the order of black salve was not delivered, it was back ordered. However, an interesting point is raised. Plaintiff asserts that he can sell black salve in the state of his residence or place of manufacture. Basis for argument, the recent marijuana laws in Colorado and Washington. Marijuana is illegal federally, however the federal government acknowledges the states right of sovereignty and do not persecute those

individuals that process marijuana that is within the amounts the state permits. Therefore, Plaintiff asserts that the United States Food and Drug Administration has no authority on products he sells and/or manufactures to entities and individuals whom reside in the state of Montana, the jurisdiction falls under the state of Montana and their dietary supplement division and its regulations.

Count IV. Plaintiff alleges that Defendant's letter served on or about January 2014 requiring him to shut down and cease post on a social media web site violates his right to free speech guaranteed by both the United States Constitution and Constitution of Montana.

Date of incident: On or about January 9, 2014 to present.

Supporting facts: Defendant Mariam Burbach served Plaintiff a registered letter on or about January 9, 2014 requiring Plaintiff to shut down his facebook page along with numerous other demands. Plaintiff complied and has ceased posting on any social media sites . As other points, those will addressed in other courts. As for the social media posting, the United Supreme court ruled that social media is a form of fee speech. Therefore, such a demand is a violation of Plaintiff's right to free speech.

Count V. Defendant Mariam Burbach sent a letter to Plaintiff stating he must remove all products from Amazon and his web sites, Plaintiff asserts that the Product Lugol's iodine is grandfathered in and is not subjected to the providions of the consent decree.

Date of incident: On or about January 9, 2014 to present

Supporting Facts: Defendants in the letter dated January 9, 2014 required that he remove all products of Amazon and his web site and cease manufacture of all

supplements. After it was presented at the just cause hearing on or about October 013, that Plaintiff needed to have a written document from the United States Food and Drug Administration stating whether labels comply with their requirements. After learning that it must in fact be in writing Plaintiff removed those products. The only products Plaintiff offers is Lugol's Iodine, this product is made the same way as Joseph Lugols made it in 1824, prior to the creations of the United States Food and Drug Administration.

Therefore, based on Defendants own grandfather clause regarding supplements, Lugol's Iodine falls well within those perimeters. As for other supplements, Plaintiff has ceased producing and manufacturing for interstate sales and the only products that Plaintiff sells over state lines where the United States Food and Drug Administration has jurisdiction is Lugol's Iodine and the product is grandfathered in as defined by the Defendants own regulations. There is no difference in formula with Lugols, the ingredients are iodine, potassium iodide and distilled water. Where other product Plaintiff produces and sells over state lines contain proprietary blends of herbs. Therefore, Plaintiff removed from Amazon, Ebay and his web sites those products so they are not available to the general public.

Count IV. A representative of Defendants stated in a press release were slanderous. Defendants stated that they persecuted Plaintiff and his company because they posed a health risk to the public.

Date of the Incident: On or about January 2014.

Supporting facts: In the just cause hearing on or about October 1013 counsel for Defendants stated that the only issue was the labels. Specifically, the source of whom completed the labels and whether they were an out side source. Therefore, there is no

issue as to risk to the public. The statement sounded as though the products produced by Plaintiff posed a health risk to the public. Such is not the case, wording and whom created the wording on a supplement label does not put the public at risk. Especially, when the labels make no medical claim. Therefore, such a statement was slanderous to Plaintiff, his company and products his company produces and sells.

V. INJURIES

As a result of Defendants actions Plaintiff has lost revenue for the restrictions and prohibited sales of numerous nutritional products. Defendants definition of that dietary supplements and nutritional supplements are the same are outdated and in conflict with present scientific and research data. Dietary supplements can contain fillers, binders, and synthetic ingredients. Whereas Nutritional supplements contain only natural plants, herbs, spices and botanicals and contain no fillers, binders or synthetic ingredients. Plaintiff has lost revenues by Defendants actions and inaction on not providing a written document regarding Plaintiff's labels. At the Just Cause Hearing held on or about October 2013, counsel for the Defendants specifically stated that the only issue of concern is the labels. There was no issue as to the quality of ingredients or how the products are manufactured it is specifically stated in court records; wording on labels. Defendants released a comment to the press stating the issue for the fine and prosecution by the United States Food and Drug Administration is to protect the public's safety. This point could actually be account of slander. How can the wording on a label put the public at risk, there are not statements that Plaintiff's products would cure, treat or prevent any disease. However, based on scientific evidence and research done at numerous universities across the United States herbs, spices and botanicals can prevent numerous

diseases. Specifically but not limited to Cinnamon, is a scientific fact that cinnamon reduces blood sugar levels. Also white willow bark is good for pain, that's right it is commonly called Aspirin now. Just based on being prohibited from selling black salves, Plaintiff loses between \$8,000 to \$12,000 her month and now being prohibited from selling other nutritional supplements or being able to speak and express on social media Plaintiff loses and additional income of \$12,000 to \$18,000 per month. Therefore, Plaintiff loses between \$20,000 and \$30,000 per month. This is not counting the restriction that the Defendants placed on Plaintiff so his company can not expand.

Plaintiff further alleges that some of the actions be Defendants is based on his spiritual and political beliefs and affiliation, Plaintiff is a strong and staunch conservative and supports the Tea Party and other conservative organizations.

VI. REQUEST FOR RELIEF

Plaintiff requests and prays for the following relief or as this court or the law allows or deems just:

1. Immediate injunctive relief staying the Defendants from any further actions or pending retaliatory actions until this cause of litigation is disposed of decided.
2. Written acceptance documentation of labels submitted to the Defendants at plaintiff's residence. Plaintiff is a resident of the state of Washington, Seattle District and all other future labels that will be submitted on behalf of Plaintiff. As an outside label expert, Plaintiff will use the state of Montana and its process of licensing supplements products.
3. That the Defendants do not have regulatory authority when Plaintiff sells his supplements within his state of residence which is intrastate.

4. That Defendants undated its regulations and definitions as to the difference between dietary supplements and nutritional supplants.

5. Compensatory damages in the amount of Three Million Two Hundred Thousand Dollars (\$ 3,200,000.00) for lost revenue for being denied sale and manufacture of numerous supplements that Plaintiff's company manufactures and sells to the general public.

6 Punitive damages on the in the amount of One Hundred Twenty Eight Thousand Dollars (\$128,000,000.00) for mental, emotional stress by the actions and slanderous comments and defamation by Defendant's actions that directly and indirectly effect Plaintiff.

VII. PLAINTIFFS DECLARATION

A. I understand I must keep the Court informed of my current mailing address and failure to do so may result in dismissal of my case without notice to me;

B. I understand the Federal Rules of Civil Procedure prohibits litigants filing complaints using curtain information in documents submitted to the court. In order to comply with these rules, I understand that:

- * social security numbers, taxpayer identification numbers, and financial account numbers must include only the last four didgets (e.g. xxx-xx-2311, xxxxxx4593)

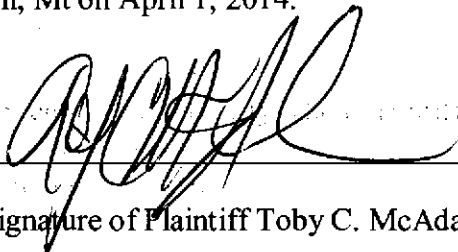
- * birth dates must include the year of birth only (e.g. xx/xx/2014)

- * names of persons under the age of 18 must be initials only (e.g. T.M)

If my documents, including exhibits, contain any of the above information, I understand it is my responsibility to black out that information out before sending those documents to the Court. I am responsible for protecting privacy of this information.

I declare under penalty of perjury that I am the Plaintiff in this action, I have read this complaint, and the information I set forth herein as true and correct to the best of my knowledge. 28 U.S.C. § 1746; 18 U.S.C. § 1621.

Executed at 105 S. 9th Street Livingston, Mt on April 1, 2014.



Signature of Plaintiff Toby C. McAdam